METHOD OF ADMINISTERING A THERAPEUTICALLY ACTIVE SUBSTANCE

CROSS REFERENCE TO RELATED APPLICATIONS

The present application claims the priority of U.S. provisional application No. 60/249,128 filed Nov. 16, 2000.

STATEMENT AS TO FEDERALLY SPONSORED RESEARCH

Not applicable.

FIELD OF THE INVENTION

The invention relates generally to the fields of medicine and delivery of therapeutically active substances. More particularly, the invention relates to implantable brachytherapy devices.

BACKGROUND

Radioactive seed therapy, commonly referred to as brachytherapy, is an established technique for treating various medical conditions, most notably prostate cancer. In a typical application of brachytherapy for treating prostate cancer, about 50–150 small seeds containing a radioisotope that emits a relatively short-acting type of radiation are surgically implanted in the diseased tissue. Because the seeds are localized near the diseased tissue, the radiation they emit is thereby concentrated on the cancerous cells and not on distantly located healthy tissue. In this respect, brachytherapy is advantageous over conventional external beam radiation.

A number of devices have been employed to implant radioactive seeds into tissues. See, e.g., U.S. Pat. No. 2,269,963 to Wappler; U.S. Pat. No. 4,402,308 to Scott; U.S. Pat. No. 5,860,909 to Mick; and U.S. Pat. No. 6,007,474 to Rydell. In a typical protocol for treating prostate cancer, an implantation device having a specialized needle is inserted through the skin between the rectum and scrotum into the prostate to deliver radioactive seeds to the prostate. The needle can be repositioned or a new needle used for other sites in the prostate where seeds are to be implanted. Typically, 20–40 needles are used to deliver between about 50–150 seeds per prostate. A rectal ultrasound probe is used to track the position of the needles. Once the end of a given needle is positioned in a desired location, a seed is forced down the bore of the needle so that it becomes lodged at that location.

As the seeds are implanted in the prostate as desired, the needles are removed from the patient. Over the ensuing several months the radiation emitted from the seeds kills the cancerous cells. Surgical removal of the seeds is usually not necessary because the type of radioisotope generally used decays over the several month period so that very little radiation is emitted from the seeds after this time.

Currently marketed radioactive seeds take the form of a capsule encapsulating a radioisotope. See, e.g., Symmetra® I-125 (Bebig GmbH, Germany); Iogold™ I-125 and Iogold™ Pd-103 (North American Scientific, Inc., Chatsworth, Calif.); Best® I-125 and Best® Pd-103 (Best Industries, Springfield, Va.); Brachyseed® I-125 (Draximage, Inc., Canada); Intersource® Pd-103 (International Brachytherapy, Belgium); Oncoseed® I-125 (Nycomed Amersham, UK); STM 1250 I-125 (Sourcetech Medical, Carol Stream, Ill.); Pharmaseed® I-125 (Syncor, Woodland Hills, Calif.); Prostaseed™ I-125 (Urocor, Oklahoma City, Okla.); and I-plant® I-125 (Implant Sciences Corpation, Wakefield, Mass.). The capsule of these seeds is made of a biocompatible substance such as titanium or stainless steel, and is tightly sealed to prevent leaching of the radioisotope. The capsule is sized to fit down the bore of one of the needles used in the implantation device. Since most such needles are about 18 gauge, the capsule typically has a diameter of about 0.8 mm and a length of about 4.5 mm.

The two radioisotopes most commonly used in prostate brachytherapy seeds are iodine (I-125) and palladium (Pd-103). Both emit low energy irradiation and have half-life characteristics ideal for treating tumors. For example, I-125 seeds decay at a rate of 50% every 60 days, so that using typical starting doses their radioactivity is almost exhausted after ten months. Pd-103 seeds decay even more quickly, losing half their energy every 17 days so that they are nearly inert after only 3 months.

Radioactive brachytherapy seeds may also contain other components. For example, to assist in tracking their proper placement using standard X-ray imaging techniques, such seeds may contain a radiopaque marker. Markers are typically made of high atomic number (i.e., "high Z") elements or alloys or mixtures containing such elements. Examples of these include platinum, iridium, rhenium, gold, tantalum, lead, bismuth alloys, indium alloys, solder or other alloys with low melting points, tungsten, and silver. Many radiopaque markers are currently being marketed including: platinum/iridium markers (Draximage, Inc. and International Brachytherapy), gold rods (Bebig GmbH), gold/copper alloy markers (North American Scientific), palladium rods (Syncor), tungsten markers (Best Industries), silver rods (Nycomed Amersham), silver spheres (International Isotopes Inc. and Urocor), and silver wire (Implant Sciences Corp.). Other radiopaque markers include polymers impregnated with various substances (see, e.g., U.S. Pat. No. 6,077,880).

A number of different U.S. patents disclose technology relating to brachytherapy. For example, U.S. Pat. No. 3,351,049 to Lawrence discloses the use of a low-energy X-ray-emitting interstitial implant as a brachytherapy source. In addition, U.S. Pat. No. 4,323,055 to Kubiatowicz; U.S. Pat. No. 4,702,228 to Russell; U.S. Pat. No. 4,891,165 to Suthanthiran; U.S. Pat. No. 5,405,309 to Carden; U.S. Pat. No. 5,713,828 to Coniglione; U.S. Pat. No. 5,997,463 to Cutrer; U.S. Pat. No. 6,066,083 to Slater; and U.S. Pat. No. 6,074,337 to Tucker disclose technologies relating to brachytherapy devices.

SUMMARY

The invention relates to a brachytherapy seed that includes a drug or other therapeutically active substance that can be delivered to a subject upon implantation into the subject through the bore of a brachytherapy implantation needle. Because the brachytherapy seeds of the invention can be sized and shaped to fit through the bore of a brachytherapy implantation needle, they are suitable for use with brachytherapy seed implantation instruments such as an implant needle, a Henschke, Scott, or Mick applicator, or a like device such as a Royal Marsden gold grain gun. A drug or other therapeutically active substance can be included in the seed in addition to, or as an alternative to, a radioisotope. A drug or other therapeutically active substance can also be associated with a biodegradable component so that its rate of release in the implantation site can be controlled according to the rate that the biodegradable substance decomposes at the implantation site. Thus, like conventional radioactive